K091345

2 510(k) Summary

JUN 12 2009

Date Prepared: April 15, 2009

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Loucinda Bjorklund
Senior Regulatory Affairs Associate
Tel: 763.656.4208 (direct); Fax: 763.656.4253
Email: lbjorklund@vascularsolutions.com

General Information

Trade Name	Gopher™ Gold catheter
Common / Usual Name	Percutaneous catheter
Classification Name	870.1250 Catheter, percutaneous
Predicate Device	K070372 Gopher catheter (Vascular Solutions, Inc.)

Device Description

The Gopher Gold catheter is a 3F catheter that is compatible with standard 0.014" guidewires and 6F guide catheters. The Gopher Gold is a single-lumen catheter with a working length of 135 cm with printed positioning marks at 95 cm and 105 cm. The Gopher Gold catheter is packaged in a dispenser coil and is sealed within a single sterile barrier pouch. The Gopher Gold catheter is sterilized by ethylene oxide and intended for single use.

Intended Use / Indications

The Gopher Gold catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents

Substantial Equivalence and Summary of Studies

The Gopher gold catheter is substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and other design verification testing, the results of which did not raise any new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

Vascular Solutions, Inc.
c/o Ms. Loucinda Bjorklund
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K091345
Trade/Device Name: Gopher™ Gold Catheter
Common Name: Catheter, Percutaneous
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: May 5, 2009
Received: May 13, 2009

Dear Ms. Bjorklund:

This letter corrects our substantially equivalent letter of June 12, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091345

Device Name: Gopher™ Gold catheter

Indications for Use:

The Gopher Gold catheter is intended to be used in conjunction with steerable guidewires to access discreet regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic and therapeutic agents.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

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